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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,171

05/04/2006

Ulrike W. Klueh

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EXAMINER

SAJJADI, FEREDYDOUN GHOTB

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

12/01/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/578,171	<b>Applicant(s)</b> KLUEH ET AL.	
	<b>Examiner</b> FEREYDOUN G. SAJJADI	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,9,14-16,19,20,25,27,28,37-39,51.52,54,59 and 66-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-4,9,14-16,19,20,25,27,28,37-39,51.52,54,59 and 66-75 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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**DETAILED ACTION*****Claim Status***

This action is in response to papers filed August 29, 2008. Applicant's response to restriction requirement of June 27, 2008 has been entered. Claims 29, 35, 36, 50, 53, 57 and 60-62 have been cancelled. Claims 59 has been amended and claims 66-75 newly added. Currently, claims 1-4, 9, 14-16, 19, 20, 25, 27, 28, 37-39, 51, 52, 54, 59 and 66-75 are pending in the application. Please note that the examiner assigned to this Application has changed.

***Response to Election/Restrictions***

Applicants' election of Group I (claims 1-4, 9, 14-16, 19, 20, 25, 27, 28, 37-39, 51, 52, 54 and 59), drawn to an artificial tissue system or an artificial implant system comprising said artificial tissue system, is acknowledged. Applicants' remarks with regards to the teachings of Soykan (U.S. Patent No.: 6,824,561), that allegedly fail to meet several limitations of the claims has been treated as constituting a traversal of the restriction requirement. However, it should be noted that the prior art of Soykan was applied against the same or corresponding special technical feature shared by the distinct inventions, i.e. an artificial tissue system. The prior art of Soykan was therefore correctly applied with respect to an artificial tissue system, though the lack of unity is moot in view of Applicants' cancellation of non-elected inventions.

However, the pending claims are subject to further restriction as set forth below, necessitated in part by Applicants' claim amendments. It should be noted that restriction between plural, distinct inventions is discretionary on the part of the examiner in utility patent applications (see MPEP § 803), and since 37 CFR 1.142(a) provides that restriction is proper at any stage of prosecution up to final action, a second requirement may be made when it becomes proper, even though there was a prior requirement with which applicant complied. *Ex parte Benke*, 1904 C.D. 63, 108 O.G. 1588 (Comm'r Pat. 1904) (See MPEP § 811.02).

Applicant timely responded to the restriction (election) requirement in the Paper filed August 29, 2008.

***New Species Election/Restrictions***

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This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Biological, engineered, support, stem, artificial and hybrid cells, as recited in claim 2.

Biological, engineered, synthetic and hybrid matrices, as recited in claim 20.

Gel, paste and polymer, as recited in claim 25.

Inflammation and fibrosis, as recited in claim 59.

Basement membrane and normal vascular stem cells; (basement membrane and cytokines bound to basement membrane) and normal vascular stem cells; basement membrane and normal vascular stem cells and engineered support cells; basement membrane and normal vascular stem cells and engineered stem cells; (basement membrane and cytokines bound to the basement membrane) and normal vascular stem cells and engineered support cells; or (basement membrane and cytokines bound to the basement membrane) and normal vascular stem cells and engineered stem cells.

Applicant is required, in reply to this action, to elect a single species of cells, matrices, gel, paste, polymer, inflammation, fibrosis and a basement membrane/cell complex, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1, 27, 28, 37, 39, 74, 75, and claims dependent therefrom correspond to all the species listed above.

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The following claim(s) are generic: 1-4, 9, 14-16, 19, 20, 25, 27, 28, 37-39, 51, 52, 54, 59 and 66-75.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical feature of the different cell types, matrices, gel, paste, polymer, inflammation, fibrosis, and basement membrane compositions, linking the members does not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/  
Examiner, Art Unit 1633